REMARKS

Status of the Claims

Claims 1 to 94 have been cancelled. Claims 95-101 have been amended. Claims 95-109 are pending and under consideration.

Claims 102-108 are allowed. Claim 95 is objected to for informalities. Claims 96-101 are rejected under 35 U.S.C. 102 for being anticipated by the Riss publication. Claim 109 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The objection of Claim 95

Claim 95 is objected to for informalities, because cell line T47D is repeated in the claim. Claim 95 is amended to remove the repeated cell line T47D.

The rejection of Claims 96 to 101

Claims 96-101 are rejected under 35 U.S.C. 102 for being anticipated by the Riss publication where it was asserted that it disclosed a method wherein GH4C1 cell line is grown in either serum free or serum supplemented growth medium and exposed to phenol red in the presence or absence of estrogen, as depicted in Fig. 2 and 3 of Riss. It was asserted that phenol red is a substance of interest. It was also asserted that the presence of serum provided the limitation of treating a sample with either IgM or IgA, because serum inherently comprises secretory immunoglobulins, and that the presence of serum also provides an inhibitory amount of IgM or IgA, because the inhibition is clearly reversed by the addition of estrogen (Fig. 2 in Riss) as referenced by the office on page 5 of the Office Action.

The examiner asserted that the "wherein" clauses of claims 96 to 101 are not given patentable weight in page 4 of the Office Action. Claims 96 to 101 have been amended to remove the "wherein" clauses and to include an active step of detecting,

(claims 96 and 97 to detecting inhibition of steroid hormone responsive cell growth and claims 98 to 101 to detecting estrogenic activity). Thus, the inclusion of this active step should provide patentable weight to these steps of the method differentiating these claims from the prior art so these claims should now not be anticipated by the method disclosed in Riss.

Claims 100 and 101 require at least three different experimental conditions be carried out for the method. It was asserted that the Riss anticipated this requirement of three different samples because the testing was done in triplicate as indicated in Fig. 2-6, as referenced by the office on page 5 of the Office Action. However, testing in triplicate in Riss (and in general in science) means that the same experimental conditions are run three times to obtain an average result. This was the reason given for the triplicate runs in Riss ("The values represent the mean of triplicate wells", Riss, Fig 2-6). The three samples required in claims 100 and 101 are at different experimental conditions (with the substance of interest added, with estrogen added and without either added) and would not be termed triplicate runs. Therefore, the triplicate runs of Riss do not anticipate the three different experimental conditions described in claims 100 and 101.

Claims 96 to 101 are also amended to specify that purified IgM or purified IgA is used in the methods. Support for using purified IgM or IgA can be found at least at pages 103-04, paragraphs [0379] to [0381] of the original application as filed (pages 50-51, paragraphs [0536] to [0541] of the published application). Thus, the use of serum in Riss instead of purified IgM or purified IgA does not now anticipate the amended claims 96 to 101, because Riss never makes mention to IgA or IgM, and it was not until the present disclosure that the identity of the inhibitor in serum was identified as IgA and IgM. Also, the use of serum in Riss is not the same as using purified IgA or IgM because serum contains so many other species that could render the methods of the claims unreliable. For example, the extraction method used in Riss (extraction for a shorter time at higher temperature) to remove hormones present in the serum which would induce growth is not as effective as presented in the current application. Most notably, for the present application, the temperature of the charcoal extraction was reduced from 56°C (Riss, p.137) to 34°C (original application, pp 38-39, paragraph [0226]), the time of extraction increased from 15 minutes (Riss, p.137) to two

extractions for 2 hours each (original application, pp 38-39, paragraph [0226]), and a new XAD-4 resin method introduced. Thus, if the extraction did not remove enough of the hormone growth factors, these could induce growth and mask an inhibitory effect of any immunoglobulins present in the serum, and conversely, other factors in the serum could induce an inhibitory effect by other means when none should be present. The use of serum instead of purified IgM or purified IgA in the present method could produce unreliable results, therefore the use of serum in accordance with the present methods would not inherently anticipate the use of a purified immunoglobulin.

Therefore, in light of the amendments and comments, it is respectfully requested that the rejections under 35 U.S.C. 102 be withdrawn as to claims 96 to 101, and the claims be allowed.

The rejection of Claim 109

Claim 109 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "H-301" in claim 109 lacks antecedent basis. Claim 95 is amended to add reference to cell line "H-301", providing antecedent basis for claim 109. The specification supports the addition of this cell line at least at page 33, Table 1 and at pages 87-88, paragraph [0339] of the original application as filed (page 43, paragraphs [0463] to [0464] in the published application) in example 12. Because claim 109 now has antecedent basis in claim 95, the Applicant respectfully requests the rejection under 35 U.S.C. 112 be withdrawn, and claim 109 be allowed.

Because the pending claims, when properly understood, particularly point out and distinctly claim the subject matter Applicant regards as his invention, the pending claims are based on an adequate written description, and the pending claims are fully supported by Applicant's specification as originally filed, Applicant respectfully requests that the current rejections be withdrawn and that all the claims be allowed.

Respectfully submitted,

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